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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/747,865	12/29/2003	Benjamin Oshlack	200.1134 CON	2763

7590 01/27/2005

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/747,865	OSHLACK ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9-36* is/are rejected.

7)☒ Claim(s) *8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040907*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The abstract of the disclosure is objected to because of the presence of legal terminology. Each occurrence of the word "said" should be changed to "the". Correction is required. See MPEP § 608.01(b).

2. The disclosure is objected to because of the following informalities: The status of parent application 09/781,076 should be updated in the claim for priority inserted into the specification by the preliminary amendment. At page 3, line 13, "bimodally" is misspelled. At page 3, line 27, "treatment" is misspelled. At page 7, line 22, "the" (first occurrence) should not be capitalized. At page 8, line 18, "opioid" (second occurrence) is misspelled. At page 10, line 25, and page 35, line 33, the second period in each line should be deleted. At page 16, line 34, it is believed that "patch" should be inserted after "transdermal". Appropriate correction is required.

3. Claims 13, 14, 18, 22, 27, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase "the oral dosage form" at claim 13, line 1. The claims upon which claim 13 depends do not mention oral administration. At claim 14, line 5, the "preferably..." phrase is indefinite because it is not clear if the claim is to be limited to the preferred embodiment or not. It is suggested that the word "preferably" could be deleted from the claim. There is no antecedent basis in the claims for the phrase "the opioid receptor antagonist" at claim 18, lines 1-2. Note that the claim upon which claim 18 depends does not mention opioid receptors. It is suggested that the word "receptor" be deleted from claim 18. For analogous reasons, it is suggested that the word "receptor" be deleted from claims 22, 27, and 34.

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-4, 6, 10, and 15-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,716,449. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '449 patent anticipate instant claims 1-4, 6, 10, 15-17, 19-21, 23-26, 28-33, 35, and 36. Because the same active agents are present and are administered in the same controlled release dosage form at the same proportionate rate such that the antagonist attenuates a side effect of the agonist, inherently the antagonist will attenuate the same side effects of the agonist to the same degree in the claimed invention of the '449 application as in the instant claimed invention. With respect to instant claims 18, 22, 27, and 34, although the '449 patent does not claim any relative amounts for the agonist and antagonist, it would have been obvious to one of ordinary skill in the art to determine all operable and optimal proportions for the agonist and antagonist in the claimed invention of the '449 patent because amounts and proportions are art-recognized result-effective variables which are routinely determined and optimized in the pharmaceutical arts.

6. Claims 1-5, 10, 11, 15, 16, 19, 21, 23, 24, 26, 32, and 33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims 1-32, 34-37, and 39-44 of copending Application No. 10/199,972. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '972 application anticipate the instant claims. Because the amounts of naloxone claimed in the '972 application are of the same order (i.e., less than 1 mg) as the amounts of opioid antagonist disclosed in Applicants' examples, the amounts of naloxone claimed in the '972 application are deemed to be sub-analgesic amounts. Alternatively, the term "sub-analgesic" is a process limitation, its scope depending upon the species and size of the animal to which the composition is to be administered. Inherently there exists an animal of such a species and size for which the amounts of naloxone claimed in the '972 application are sub-analgesic. With respect to the attenuated side effects and the enhanced analgesic potency recited in the instant claims, because the same active agents are present and are administered in the same controlled release dosage form at the same proportionate rate, inherently the naloxone will attenuate the same side effects and enhance the analgesic potency of the oxycodone to the same degree in the claimed invention of the '972 application as in the instant claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1-5, 16-19, 21-23, 26-28, 33, and 34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of copending Application No. 10/214,413. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '413 application anticipate the instant claims. Because the ratio of antagonist to agonist set forth in claim 30 of the '413 application is the same as claimed in the instant application, the amounts of

antagonist claimed in the '413 application are deemed to be sub-analgesic amounts. Alternatively, the term "sub-analgesic" is a process limitation, its scope depending upon the species and size of the animal to which the composition is to be administered. Inherently there exists an animal of such a species and size for which the amounts of naloxone claimed in the '413 application are sub-analgesic.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Instant claims 1-36 are deemed not to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/181,358 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, does not disclose the release of sub-analgesic amounts of the opioid agonist; does not disclose the opioid antagonists diprenorphine, etorphine, or dihydroetorphine; and does not disclose opioid antagonists in amounts as low as 1000 fold less than the amounts of opioid agonist. Accordingly, the WO Patent Application 99/32120 and the WO Patent Application 00/01377 are available as prior art against these claims under 35 U.S.C. 102(b).

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1, 4, 5, 9, 15-17, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 99/32120. The WO Patent Application '120 teaches oral dosage forms of an opioid analgesic, which can be in sustained release form and which comprise a combination of an opioid agonist and an opioid antagonist. In particular, the opioid agonist can be hydromorphone, oxycodone, or morphine, and the opioid antagonist can be naltrexone. See, e.g., the Abstract and page 8, lines 1-9. Use of the combination of opioid agonist and antagonist reduces the abuse potential of the opioid agonist and attenuates the possibility of physical dependence upon the opioid agonist (see, e.g., page 6, lines 5-12, and page 8, lines 14-24). The sustained release form permits administration on a twice-a-day or a once-a-

day basis and can provide analgesia for about 24 hours (see, e.g., page 8, lines 25-28, and page 21, lines 21-25). The sustained release carrier can be present either a matrix or as a coating, and the oral dosage form can be granules, spheroids, beads, or pellets (see, e.g., page 8, line 25 - page 9, line 1, and page 20, lines 10-11).

11. Claims 2, 18, 21-30, and 33-36 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 99/32120 as applied against claims 1, 4, 5, 9, 15-17, 19, and 20 above, and further in view of Crain et al (U.S. Patent No. 5,767,125). The WO Patent Application '120 teaches the oral administration of combinations of opioid agonists and opioid antagonists where the opioid antagonist reduces the abuse potential of and attenuates physical dependence upon the opioid agonist, but does not teach amounts of opioid antagonists which enhance the potency of the opioid agonist or which reduce side effects of the opioid agonist such as anti-analgesia, hyperalgesia, hyperexcitability, and tolerance, and does not teach opioid antagonist amounts of 100 to about 1000 fold less than the amounts of opioid agonist. Crain et al teach the oral administration of combinations of opioid agonists and opioid antagonists where the opioid antagonist enhances the potency of the opioid agonist and reduces the side effects of the opioid agonist such as anti-analgesia, hyperalgesia, hyperexcitability, and tolerance. To achieve these results, Crain et al administer their opioid antagonists in amounts at least 100-1000 fold less than the amount of the opioid agonist. Because of the potency-enhancing effect of the opioid antagonist, lesser amounts, including sub-analgesic amounts, of the opioid agonist can be used. See, e.g., the Abstract; column 5, lines 9-22 and 41-47; column 6, lines 7-36; and claim 4. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to administer the opioid agonists and antagonists of the WO Patent Application '120 in

the amounts and proportions taught Crain et al because Crain et al's amounts and proportions are taught to be applicable to a wide variety of administration means, and because Crain et al's proportions provide the benefit of enhanced potency of the opioid agonist while permitting the use of lower amounts and with fewer side effects while still achieving a goal of the WO Patent Application '120 of reducing the specific side effect of physical dependence on the opioid agonist.

12. Claims 3 and 10-14 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 99/32120 as applied against claims 1, 4, 5, 9, 15-17, 19, and 20 above, and further in view of the WO Patent Application 00/01377 or Simon (U.S. Patent No. 6,103,258). The WO Patent Application '120 does not teach releasing the opioid agonist and antagonist at substantially proportionate rates. The WO Patent Application '377 teaches co-administration of opioid agonists and antagonists by intramuscular, intravenous, nasal, oral, sublingual or transdermal methods, recognizes that the individual components can have different pharmacokinetic profiles and different in vivo life spans, and teaches providing a controlled release matrix or coating to the shorter-acting component so that its pharmacokinetic profile better matches the profile of the longer-acting component, i.e. so that their release rates are proportional. See, e.g., page 17, line 22 - page 18, line 26; page 22, lines 20-22; page 22, line 30 - page 23, line 8. Simon is the U.S. equivalent of the WO Patent Application 00/01377 and contains the same disclosure as that of the WO Patent Application '377 (see, e.g., column 9, line 39 - column 10, line 18, and column 12, lines 33-60). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to provide controlled release matrices or coatings as taught by the WO Patent Application '377 and Simon to the agonist or

antagonist of the WO Patent Application '120 so that the problem of different pharmacokinetic profiles and in vivo lifespans is avoided.

13. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 99/32120 in view of Crain et al (U.S. Patent No. 5,767,125) as applied against claims 2, 18, 21-30, and 33-36 above, and further in view of the WO Patent Application 00/01377 or Simon (U.S. Patent No. 6,103,258). The WO Patent Application '120 does not teach releasing the opioid agonist and antagonist at substantially proportionate rates. The WO Patent Application '377 teaches co-administration of opioid agonists and antagonists by intramuscular, intravenous, nasal, oral, sublingual or transdermal methods, recognizes that the individual components can have different pharmacokinetic profiles and different in vivo life spans, and teaches providing a controlled release matrix or coating to the shorter-acting component so that its pharmacokinetic profile better matches the profile of the longer-acting component, i.e. so that their release rates are proportional. See, e.g., page 17, line 22 - page 18, line 26; page 22, lines 20-22; page 22, line 30 - page 23, line 8. Simon is the U.S. equivalent of the WO Patent Application 00/01377 and contains the same disclosure as that of the WO Patent Application '377 (see, e.g., column 9, line 39 - column 10, line 18, and column 12, lines 33-60). It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to provide controlled release matrices or coatings as taught by the WO Patent Application '377 and Simon to the agonist or antagonist of the WO Patent Application '120 so that the problem of different pharmacokinetic profiles and in vivo lifespans is avoided.

14. Claims 1, 4, 5, 9, 15-17, 19, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Palermo et al (U.S. Patent No. 6,228,863); claims 2, 18, 21-30, and 33-36 are

rejected under 35 U.S.C. 103(a) as being obvious over Palermo et al in view of Crain et al (U.S. Patent No. 5,767,125); claims 3 and 10-14 are rejected under 35 U.S.C. 103(a) as being obvious over Palermo et al in view of the WO Patent Application 00/01377 or Simon (U.S. Patent No. 6,103,258); and claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 99/32120 in view of Crain et al (U.S. Patent No. 5,757,125) and further in view of the WO Patent Application 00/01377 or Simon (U.S. Patent No. 6,103,258). Palermo et al is the U.S. equivalent of the WO Patent Application 99/32120 applied above, contains the same disclosure as that of the WO Patent Application '120 relied upon in the above rejections, and accordingly anticipates or renders obvious the claims for the same reasons set forth in the above rejections. Application of Crain et al, the WO Patent Application '377, and Simon is the same as in the above rejections.

15. Claims 1-4, 6, 10, 18-23, 26-28, and 32-34 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 00/01377 in view of Reder et al (U.S. Patent No. 5,968,547). The WO Patent Application '377 teaches transdermal administration of an analgesic combination of fentanyl and nalmefene. The presence of the nalmefene increases the potency of the opioid agonist while decreasing side effects such as the possibility of physical dependence upon the opioid agonist. The proportions of agonist to antagonist exemplified in the WO Patent Application '377 range from about 100 to about 1000 fold less for the antagonist. See, e.g., page 9, lines 21-29; page 14, lines 16-19; page 18, lines 1-26; page 19, lines 22-24; page 21, lines 29-30; and page 22, lines 20-28. The WO Patent Application '377 is not limited to any particular transdermal delivery system, but does not teach one with a delivery time of at least 3 days. Reder et al teach administration of an opioid agonist using a transdermal delivery system which

releases the agonist over a period of 5 days. See, e.g., the abstract and claim 1. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to administer the analgesic combination of the WO Patent Application '377 using the transdermal delivery system of Reder et al because the WO Patent Application '377's analgesic combination can be administered using any transdermal delivery system, because Reder et al's transdermal system is used to deliver analogous compounds for the same analgesic purpose, and because use of Reder et al's transdermal system will permit long-time pain relief with minimal intrusion to the patient.

16. Claims 1-4, 7, 10, 18-23, 26-28, and 32-34 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 00/01377 in view of Chasin et al (U.S. Patent No. 5,942,241). The WO Patent Application '377 teaches administration of an analgesic combination of an opioid agonist and nalmefene. Administration can be by any known method, such as intramuscular. The presence of the nalmefene increases the potency of the opioid agonist while decreasing side effects such as the possibility of physical dependence upon the opioid agonist. The proportions of agonist to antagonist exemplified in the WO Patent Application '377 range from about 100 to about 1000 fold less for the antagonist. See, e.g., page 9, lines 21-29; page 14, lines 16-19; page 18, lines 1-26; page 19, lines 22-24; page 21, lines 29-30; and page 22, lines 20-28. The WO Patent Application '377 is not limited to any particular delivery system, but does not teach an injectable formulation with a delivery time of at least 8 hours. Chasin et al teach administration of anesthetics including opioid agonists by intramuscular injection of a controlled release material which releases the active agent over a period of preferably about 1 to 24 hours or more. See, e.g., the abstract; column 6, lines 39-44; column 17, lines 2-3; and column 18, lines

29-34. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to administer the opioid agonist and antagonist combination of the WO Patent Application '377 using the intramuscular formulation of Chasin et al because the WO Patent Application '377's opioid agonist and antagonist combination can be administered using any delivery system including intramuscular delivery, because Chasin et al's intramuscular formulations are used to deliver analogous compounds, and because use of Chasin et al's intramuscular formulations will permit long-time treatment with minimal intrusion to the patient.

17. Claims 1-4, 6, 10, 18-23, 26-28, and 32-34 are rejected under 35 U.S.C. 103(a) as being obvious over Simon (U.S. Patent No. 6,103,258) in view of Reder et al (U.S. Patent No. 5,968,547); and claims 1-4, 7, 10, 18-23, 26-28, and 32-34 are rejected under 35 U.S.C. 103(a) as being obvious over Simon (U.S. Patent No. 6,103,258) in view of Chasin et al (U.S. Patent No. 5,942,241). Simon is the U.S. equivalent of the WO Patent Application 00/01377 applied above, contains the same disclosure as that of the WO Patent Application '377 relied upon in the above rejection, and accordingly renders obvious the claims for the same reasons set forth in the above rejections. Application of Reder et al and Chasin et al is the same as in the above rejections.

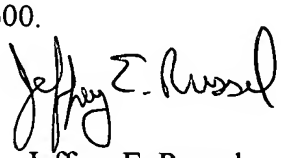
18. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record does not teach or suggest intranasal controlled release formulations which are capable of providing opioid analgesia for at least about 8 hours. The limit as disclosed in the prior art of record appears to be about 3 hours ([see, e.g., Hussain (U.S. Patent No. 4,464,378) and Illum (U.S. Patent No. 5,629,011, cited at page 20, line 29, of

the specification)], and this does not provide motivation or a reasonable expectation of success in achieving the at least about 8 hour time period claimed by Applicants.

19. The references crossed off of the Information Disclosure Statement filed September 7, 2004 were not considered because copies of the references were not provided, either in this application or during the prosecution of the parent application.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

January 25, 2005